**UNITED STATES DISTRICT COURT**
**DISTRICT OF DELAWARE**

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| In re APELLIS PHARMACEUTICALS, INC. SECURITIES LITIGATION | CA No. 1:23-cv-00834-JLH<br><br>CLASS ACTION<br><br>AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS |

Lead Plaintiffs, individually and on behalf of all others similarly situated, by their undersigned attorneys, for Lead Plaintiffs' Amended Complaint for Violations of the Federal Securities Laws, allege the following upon knowledge as to their own acts and upon the investigation conducted by their counsel. The investigation included examining and analyzing information obtained from public and proprietary sources, including, *inter alia*, United States Securities and Exchange Commission ("SEC") filings, public reports, releases, investor presentations, published interviews, news articles and other media reports, reports of securities analysts and investor advisory services, information from the United States Food and Drug Administration ("FDA"), and consultation with a world renowned expert, professor and physician. Lead Plaintiffs believe that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

## I. NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class of all persons and entities who purchased or otherwise acquired Apellis common stock between January 28, 2021 and July 28, 2023, inclusive (the "Class Period"), seeking to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), and SEC Rule 10b-5 promulgated thereunder.

2. Apellis is a commercial-stage biopharmaceutical company that focuses on the discovery, development, and commercialization of therapeutic compounds through the inhibition of the complement system for autoimmune and inflammatory diseases.

3. Apellis's "lead product candidate" includes what is now commercially referred to as SYFOVRE, an intravitreal pegcetacoplan treatment (administered through an injection into the eye) for geographic atrophy secondary to age-related macular degeneration ("AMD"). At the start of the Class Period, Apellis was in the midst of conducting two phase 3 studies on

pegcetacoplan for geographic atrophy – OAKS and DERBY. Apellis' Chief Executive Officer Cedric Francois ("Francois") acknowledged the results of those studies would be "a seminal event for our company."

4. Even assuming the FDA granted approval for the drug, the patient risk/benefit analysis was of particular importance to investors because pegcetacoplan had not demonstrated the ability to actually *improve* eyesight in patients afflicted with AMD. Rather, the data suggested only a benefit of potentially slowing the loss of eyesight from the disease. Prior to receiving the results of the studies, Defendant Francois had stated in October 2020 that a "clinically meaningful" reduction in growth of geographic atrophy for purposes of commercialization would be a "20% to 30%" reduction over the course of one year. However, the study results ultimately showed only a reduction between 16% and 22% over a one year period. As a Credit Suisse analyst noted during a September 9, 2021 report, "The pooled analysis suggests a potential benefit that is at the low end of what physicians we spoke to highlighted as meaningful."

5. Conversely, other intravitreal treatments – which by definition are administered by injection into the eye – had been linked to a risk of inflammation and other serious side effects that could result in the loss of vision. Notably, other FDA-approved intravitreal treatments had recently made headlines and lost favor among physicians and patients because they were associated with causing retinal vasculitis – inflammation of the vessels of the retina that can cause significant vision loss. Therefore, investors were concerned that if any serious risks were associated with SYFOVRE, the intended patients – the elderly – would not choose to take on the very real risks from these eye injections in exchange for a potential benefit of slightly slowing the progression of geographic atrophy, thereby limiting the financial upside to Apellis.

As a Cantor Fitzgerald analyst explained in a September 9, 2021 report: "If approved, a key factor will be how the physician community accepts the drug's profile."

6. Given these concerns, investors were thrilled as Apellis began announcing interim and final results of the OAKS and DERBY studies. While rates of inflammation and ischemic optic neuropathy (potential symptoms of retinal vasculitis) were similar to those of other intravitreal treatments that had fallen out of favor due to the risk of retinal vasculitis, Defendants went out of their way on numerous occasions to assure the market that there "were no cases of vasculitis or occlusive vasculitis" in the OAKS and DERBY trials.

7. Defendants' assurances, however, were without basis. The most commonly used and accepted test to assess the presence of vasculitis in the eye is the fluorescein angiogram, which uses fluorescent dye and a specialized camera to test for vascular leakage and macular edema. Yet, despite knowing that the risk of any adverse event, especially retinal vasculitis, was a major concern for investors and physicians that would doom the market acceptance of SYFOVRE, Apellis had not established any defined protocol in either the OAKS or DERBY studies to obtain angiography for the detection of retinal vasculitis in cases of intraocular inflammation or ischemic neuropathy. Instead, angiography was obtained at the end of the study, whether by the study running its full course or because the participant dropped out, in which case the angiography was not obtained for at least an additional 30 days. This significant delay decreased the sensitivity of identifying problems that had been treated or resolved due to the passage of time. In short, Apellis's claims of "no cases of vasculitis" were false and misleading because the studies were not designed to detect any.

8. This failure was particularly egregious because the patient dropout rate in the treatment arm of the studies was significantly higher than in the "sham" arm (where the patients

did not receive pegcetacoplan). Such a discrepancy indicated to Defendants that patients could have been dropping out of the studies because of adverse events such as inflammation, neuropathy and possibly retinal vasculitis, but the Company was unable to continue to monitor dropouts to determine if they developed vasculitis – that is, if Apellis even had an appropriate angiography protocol for detecting vasculitis.

9. After years of Defendants repeatedly proclaiming there were no cases of vasculitis observed in the studies' participants, investors began to learn the true risks of SYFOVRE on Saturday, July 15, 2023, when the American Society of Retina Specialists ("ASRS") published a letter highlighting concerns with SYFOVRE. Specifically, the ASRS indicated that physicians had actually reported six instances of occlusive retinal vasculitis, a type of inflammation that blocks blood flow through the vessels that feed the retina and potentially results in blindness.

10. On this news, the price of Apellis common stock declined $32.04 per share, or nearly 38%, from a close of $84.50 per share on Friday, July 14, 2023, to close at $52.46 per share on Monday, July 17, 2023.

11. After the market closed on July 17, 2023, Apellis issued a statement addressing the concerns raised by ASRS regarding vasculitis and SYFOVRE, explaining that, of the six occurrences of vasculitis following SYFOVRE treatment, "two of the events were confirmed as occlusive, one was confirmed as non-occlusive, and the remaining three were undetermined based on limited information and lack of imaging."

12. On this news, the price of Apellis common stock declined an additional $12.46 per share, or 23.75%, to close at $40.00 per share on July 18, 2023.

13. Prior to the open of the market on July 20, 2023, Wedbush downgraded Apellis's price target by more than 50%, from $86.00 per share to $40.00 per share.

14. On this news, the price of Apellis common stock declined $6.25 per share, or approximately 15%, from a close of $40.49 per share on July 19, 2023, to close at $34.24 per share on July 20, 2023.

15. On July 29, 2023, Apellis provided an update on the Company's review of the six events of retinal vasculitis reported by the ASRS involving SYFOVRE treatments. In the update, Apellis confirmed a seventh event of retinal vasculitis resulting from SYFOVRE treatment as determined by Apellis' internal safety committee and external retina/uveitis specialists. Apellis also stated that the Company was evaluating an eighth reported event of retinal vasculitis, which the Company had not yet confirmed.

16. On this news, the price of Apellis common stock declined $6.27 per share, or approximately 19.6%, from a close of $32.02 per share on July 28, 2023, to close at $25.75 per share on July 31, 2023.

17. As a result of Defendants' wrongful acts and omissions, and the significant decline in the market value of the Company's common stock when the truth was revealed, Plaintiffs and other members of the Class (defined below) have suffered significant damages. In all, the price of Apellis stock fell nearly 70%, from $84.50 to $25.75, wiping out almost $7 Billion in market capitalization.

## II. JURISDICTION AND VENUE

18. Plaintiffs' claims arise under Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and the rules and regulations promulgated thereunder, including SEC Rule 10b-5, 17 C.F.R. § 240.10b-5.

19. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. § 1331 and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.

20. Venue is proper in this District under Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. § 1391(b), because Apellis is incorporated in this District.

21. In connection with the acts, conduct, and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including the United States mails, interstate telephone communications, and the facilities of the national securities markets.

## III. PARTIES

22. Lead Plaintiffs Ray Peleckas and Michigan Laborers' Pension Fund purchased Apellis common stock during the Class Period, as set forth in their previously filed certifications (ECF Nos. 24-3 and 20-2), which are incorporated by reference herein, and suffered damages as a result of the violations of the federal securities laws alleged herein.

23. Defendant Apellis is a commercial-stage biopharmaceutical company that focuses on the discovery, development, and commercialization of therapeutic compounds through the inhibition of the complement system for autoimmune and inflammatory diseases.

24. Apellis is a Delaware corporation with principal executive offices at 100 Fifth Avenue, Waltham, Massachusetts, 02451.

25. Defendant Cedric Francois ("Francois") is the co-founder of Apellis and has served as a member of the Company's board of directors and as President and Chief Executive Officer since its inception. Francois received his M.D. from the University of Leuven in Belgium and his Ph.D. in physiology from the University of Louisville.

26. Apellis and Francois are collectively referred to herein as "Defendants."

27. Because of Defendant Francois' positions with the Company, he had access to the adverse undisclosed information about its business, operations, products, operational trends, financial statements, markets and present and future business prospects via internal corporate documents (including the Company's operating plans, budgets and forecasts, and reports of actual operations compared thereto), conversations and connections with other corporate officers and employees, attendance at management and/or Board meetings and committees thereof and via reports and other information provided to them in connection therewith.

28. It is appropriate to treat Defendants as a group for pleading purposes and to presume that the false, misleading, and incomplete information conveyed in the Company's public filings, press releases, and other publications as alleged herein were the result of actions by Defendant Francois. As an officer and director of Apellis, by virtue of his high-level positions with the Company, Defendant Francois directly participated in the management of the Company, was directly involved in the day-to-day operations of the Company at the highest levels, and/or was privy to confidential proprietary information concerning the Company and its business, operations, products, growth, financial statements, and financial condition, as alleged herein.

29. As an officer, director, and/or controlling person of a publicly-held company whose common stock was registered with the SEC pursuant to the Exchange Act and traded on the Nasdaq, and which is governed by the provisions of the federal securities laws, Defendant Francois had a duty to promptly disseminate accurate and truthful information with respect to the Company's financial condition and performance, growth, operations, financial statements, business, products, markets, management, earnings, and present and future business prospects, and to correct any previously-issued statements that had become materially misleading or untrue,

so that the market price of the Company's publicly-traded stock would be based upon truthful and accurate information. Defendants' false and misleading misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

30. Defendant Francois participated in the drafting, preparation, and/or approval of the various public press releases, and shareholder and investor reports and other communications complained of herein and was aware of, or recklessly disregarded, the misstatements contained therein and omissions therefrom, and was aware of their materially false and misleading nature. Because of his executive and managerial positions, and Board membership with Apellis, Defendant Francois had access to the adverse undisclosed information about Apellis's business prospects and financial condition and performance as particularized herein and knew (or recklessly disregarded) that these adverse facts rendered the positive representations made by or about Apellis and its business materially false and misleading.

31. Defendant Francois, because of his position of control and authority as an officer and director of the Company, was able to and did control the content of the various SEC filings, press releases, and other public statements pertaining to the Company during the Class Period. Defendant Francois was provided with copies of the documents alleged herein to be misleading before or shortly after their issuance and/or had the ability and/or opportunity to prevent their issuance or cause them to be corrected. Accordingly, Defendant Francois is responsible for the accuracy of the public statements detailed herein and is, therefore, primarily liable for the representations contained herein.

32. Defendant Francois is liable as a participant in a fraudulent scheme and course of conduct that operated as a fraud or deceit on purchasers of Apellis stock by disseminating materially false and misleading statements and/or concealing material adverse facts. The

scheme: (i) deceived the investing public regarding Apellis's financial reporting, business, operations, management and prospects, and the intrinsic value of Apellis's stock price; and (ii) caused Plaintiffs and the Class to purchase Apellis's publicly-traded stock at artificially inflated prices.

## IV. SUBSTANTIVE ALLEGATIONS

### A. Company Background

33. Apellis is a commercial-stage biopharmaceutical company that focuses on the discovery, development, and commercialization of therapeutic compounds through the inhibition of the complement system for autoimmune and inflammatory diseases such as geographic atrophy. Apellis's common stock trades on the Nasdaq under the ticker symbol "APLS."

34. Geographic atrophy is an advanced form of age-related macular degeneration, which is a disorder of the central portion of the retina characterized by progressive retinal cell death that ultimately leads to blindness in people aged 60 years or older.

35. Geographic atrophy involves the overactivation of the complement system, part of the body's immune system that helps the ability of antibodies and phagocytic cells to clear pathogens from an organism.

36. Since at least 2015, Apellis's "lead product candidate" had included what is now commercially referred to as SYFOVRE, a solution of pegcetacoplan that is administered through an intravitreal injection – an injection directly into the eye – for treatment of geographic atrophy.

37. Pegcetacoplan is designed to provide comprehensive control of the complement system, part of the body's immune system. It is designed to improve cell survival and reduce vascular loss in the eye by targeting complement proteins C3 and C3b, which are part of the body's immune system.

38. SYFOVRE was approved by the FDA in February 2023 for the treatment in the United States of geographic atrophy secondary to AMD.

**B. The Presence of Side Effects Were Key Concerns of the Trials**

39. SYFOVRE was approved by the FDA based on the results of two phase 3 studies, referred to as OAKS and DERBY. In these studies, Apellis claimed to have assessed the efficacy and safety of intravitreal pegcetacoplan compared with sham for the treatment of geographic atrophy secondary to AMD.

40. OAKS and DERBY were two 24-month studies, in which patients aged 60 years and older with geographic atrophy secondary to AMD were enrolled. The primary endpoint was the change from baseline to month 12 in the total area of geographic atrophy lesions in the study eye. Key secondary endpoints (measured at 24 months) were change in monocular maximum reading speed of the study eye, change from baseline in mean functional reading independence index score, change from baseline in normal luminance best-corrected visual acuity score, and change from baseline in the mean threshold sensitivity of all points in the study eye by mesopic microperimetry (OAKS only). Safety analyses included patients who were randomly assigned and received at least one injection of pegcetacoplan or sham.

41. Because SYFOVRE was administered by way of an injection directly into the eye, safety issues were of particular concern to investors because if negative side effects existed, physicians would be less likely to prescribe, and patients would be less likely to utilize the treatment. Most notable, among the potential side effects that could impact the market for the drug were: (i) inflammation, (ii) ischemic optic neuropathy, and (iii) retinal vasculitis.

42. Retinal inflammation is a debilitating condition of the retina that involves over-activation of the immune system in the eye. It can range in severity from mild, to moderate, to severe. Mild inflammation can be seen either as mild cellular infiltrate in primarily acellular

compartments (anterior chamber or vitreous cavity), or as mild vascular leakage (cystoid macular edema also known as CME).

43. More severe forms of inflammation frequently involve the retinal vessels, and in these cases the inflammation is also known as vasculitis, or it is said to have vasculitis as a component of it. Vasculitis can also vary from mild to severe to occlusive. Any inflammation left untreated has the potential to progress to more severe forms and involve the vessels.

44. Ischemic neuropathy involves blood flow impairment (ischemia) localized to the area of the optic nerve head. This is the area where the vessels enter the retina at the optic nerve.

45. In Ischemic vasculitis, the area of the retina vessels impaired is more widespread, affecting the total retina vasculature.

46. Retinal vasculitis can be an isolated condition or a complication of local or systemic inflammatory disorders characterized by inflammation of the retinal vessels. It is a sight-threatening condition that can cause complete vision loss.

47. Due to its severity and resulting impact on market acceptance for SYFOVRE, the presence of vasculitis in trial participants was critically important to the market.

48. The most commonly used and accepted test to assess the presence of vasculitis in the eye is the fluorescein angiogram, which provides the most informative imaging modality in patients with retinal vasculitis. Fluorescein angiography is routinely used in the diagnosis, monitoring and management of patients with retinal vasculitis. It involves using a fluorescent dye and a specialized camera. Signs on angiography, such as vascular leakage and macular edema can help assess the activity of the disease. Leakage of dye from vascular compartment results in perivascular hyperfluorescence.

49. Defendant Francois explained the seriousness of vasculitis and acknowledged the importance of utilizing a fluorescein angiography to properly diagnose it during a September 6, 2023 call with analysts:

> [W]hat is vasculitis? I mean vasculitis is inflammation of the blood vessels. And vasculitis on a systemic level that's typically associated with a pure autoimmune event against vessels. In the eye, what we're talking about is essentially a complication of inflammation.
>
> So severe inflammation then complicates into vasculitis, meaning when you put in fluorescein dye, it will leak from the blood vessels, right? That means the vessels are inflamed, probably as part of para-phenomenon of the overall inflammation. And then in very rare cases, that can be occlusive. That, whether you call it IOI, vasculitis occlusive that if you showed any retina doc, you will get differing opinions.

50. Similarly, during a November 28, 2023, call with analysts, Defendant Francois admitted:

> [I]t's important to note here that vasculitis is really an imaging finding, right? I mean it refers to the leakage of blood from the blood vessels in the back of the eye, which can be associated with occlusion, but which is typically a manifestation of something else, either inflammation, sometimes autoimmune disease, whatever it is.

51. Defendant Francois further acknowledged that, "vasculitis is something that can occur with intravitreal injections."

52. Defendants were therefore well aware that the use of SYFOVRE presented a risk of vasculitis because it was an intravitreal therapy and intraocular inflammation is one of the main ocular adverse events associated with intravitreal therapy. Moreover, Defendants had been conducting clinical trials for pegcetacoplan for over a decade and were intimately familiar with the potential adverse events and risks of intravitreal therapies, further confirming their knowledge that retinal vasculitis was a risk associated with intravitreal injection, such as the one utilized to administer SYFOVRE.

53. Moreover, Retinal vasculitis was of particular concern to Defendants and investors leading up to the results of the OAKS and DERBY studies in 2021 because it had recently been associated with other intravitreal treatments for macular degeneration.

54. Specifically, intravitreal administration of anti-vascular endothelial growth factor (anti-VEGF) agents is the mainstay of treatment for multiple retinal diseases, including neovascular age-related macular degeneration. Inflammatory adverse events – such as retinal vasculitis – have been associated with these medications.

55. Defendant Francois knew this full well. In fact, he had publicly discussed Novartis' Beovu (brolucizumab), which was an anti-VEGF treatment that showed vasculitis side effects shortly after receiving FDA approval and launch in 2020. The reports of vasculitis were devastating to Beovu's adoption by physicians. Specifically, in October of 2019, Novartis announced the FDA approved Beovu for the treatment of wet AMD. In February of 2020, the ASRS announced that it had received reports of inflammation following Beovu treatment, including several cases of vasculitis. Novartis ultimately concluded that there was a confirmed safety signal of rare adverse events of "retinal vasculitis and/or retinal vascular occlusion that may result in severe vision loss." This was severely damaging to the market for Beovu (as well as Novartis stock price). In response, Novartis was forced to update its label.

56. During a November 1, 2023 call with analysts, Defendant Francois discussed Novartis' Beovu:

> I mean the problem that we had is that a couple of years ago, there was another drug [Beovu] that started with this rate [of vasculitis] and ended up with a rate that was orders of magnitude worse because there was a sensitization against the drug.

57. Retinal vasculitis is also common with other anti-VEGF.

58. As Defendant Francois explained during a November 28, 2023 call with analysts:

> [V]asculitis is not something that is -- that doesn't happen in the absence of drugs being used or not, it happens with anti-VEGF injections.

### C. Although the Incident of Vasculitis Would Directly Impact the Market for SYFOVRE, Apellis Never Appropriately Tested for Vasculitis

59. Over the course of 24 months in the OAKS and DERBY trials, 419 participants were treated in the monthly arm and 420 participants in the every other month ("EOM") arm. During the trials, 3.8% and 2.1% of participants developed intraocular inflammation in the monthly arm and EOM arm, respectively. The instances of inflammation were 10-20 times that of the sham arm. Of 26 patients with intraocular inflammation at 24 months, 17 (65%) reported adverse events as mild, three (12%) as moderate, and six (23%) as severe.

60. Plaintiffs consulted with Dr. Demetrios G. Vavvas, MD, PhD. Dr. Vavvas is the Solman and Libe Friedman Professor of Ophthalmology at Harvard Medical School and Co-Director of the Ocular Regenerative Medicine Institute. Dr. Vavvas also serves as the Director of the Retina Service at Massachusetts Eye and Ear. A full-time clinician scientist, he received his ophthalmology training in the Harvard Medical School Residency Program. After serving as the Chief Resident and Director of the Eye Trauma service at Mass Eye and Ear, he completed a fellowship in Vitreoretinal Surgery there where he received the Fellow of the Year award for his resident teaching and served as the Chief Fellow. He is an active member of the retina faculty seeing a variety of surgical and medical vitreoretinal diseases. Dr. Vavvas's clinical work focuses on macular degeneration, diabetic retinopathy, trauma and oncology. He was the first to describe use of small gauge vitrectomy for complications of cataract surgery and trauma and has described a modified approach to an old surgical technique called scleral buckle in order to make it more predictable and easier to teach to trainees. Along with Drs. Dean Eliott and John B. Miller, he co-directs and organizes the Annual Fellows Course tailored for first-year vitreoretinal fellows from over 20 different programs in the nation. Dr. Vavvas closely followed the clinical

trials of pegcetacoplan/SYFOVRE and the results as they were reported. He also attended several conferences discussing the results and has made presentations and authored publications concerning the risks and benefits of the treatment.

61. According to Dr. Vavvas, "It is likely that the use of fluorescein angiogram during the clinical trial, coupled with the fact that vasculitis was 10-20x times the sham, dose dependent, and one quarter of it rated as severe, would have disclosed the risk of vasculitis and would have given us better estimation of the risk of mild, moderate or severe vasculitis."

62. Ischemic optic neuropathy was reported in 1.7% and 0.2% of participants treated monthly and EOM, respectively, and in none of the participants assigned to sham. According to Dr. Vavvas, the cases of ischemic optic neuropathy and disc edema (also known as papilledema) should have been reported together and further analyzed. "This could easily be another form of the rarer but devastating ischemic retina vasculitis…If these cases were investigated further, or more information disclosed to the community, the community would have had a better understanding of the real risk of more generalized retinal ischemia."

63. As discussed above, the prompt use of fluorescein angiogram would have identified which of these numerous instances of inflammation and ischemic optic neuropathy were also vasculitis.

64. Critically, however, ***there was no defined protocol in either the OAKS or DERBY studies to promptly obtain angiography in cases of intraocular inflammation or ischemic optic neuropathy***.

65. Notably, the Company acknowledged in a March 16, 2022 press release, "Rates of endophthalmitis and intraocular inflammation continue to be generally in line with those reported in studies of other intravitreal therapies." Despite the rates of inflammation being "in

line" with other intravitreal therapies, which themselves carried a risk of vasculitis, Apellis had no defined protocol to promptly obtain angiography in cases of intraocular inflammation or ischemic optic neuropathy. Instead, angiopathy was obtained at the end of the study, whether by the study running its full course or because the participant dropped out, in which case angiography was not obtained for at least an additional 30 days. This significant delay decreased the sensitivity of identifying problems that had been treated or resolved due to the passage of time.

66. Thus, given the risk of vasculitis with other intravitreal therapies and Defendant Francois' acknowledgment that angiography was necessary to properly diagnose it, Defendants knew, or recklessly disregarded, that they should have promptly utilized angiography before publicly proclaiming that no trial participants exhibited vasculitis.

67. In short, Defendants knew that there was a risk of vasculitis yet chose to forego any defined protocol for accurately detecting it through fluorescein angiography.

### D. The Disproportionate Dropout Rate in the Studies Indicated a Risk of Vasculitis

68. Given the disproportionate dropout rates in the treatment among the studies, it was materially false and misleading for Defendants to represent that there were no events of retinal vasculitis without a defined protocol to promptly obtain angiography in cases of intraocular inflammation or ischemic optic neuropathy.

69. In reporting the results from the OAKS and DERBY studies, Apellis presented estimated data (not actual data) from a statistical MMRM (Mixed Models for Repeated Measures) model analysis. Utilizing the model, Apellis reported a reduction in total lesion of 22%. However, the actual reduction was only 7.4%.

70. Even this reporting was materially false and misleading because the Company failed to disclose the details on all of the relevant functional metrics. As demonstrated in the following tables, all functional metrics trended worse with the treatment, suggesting that the treatment carried significant risks. Accordingly, additional disclosures indicating that all measured functions trended worse was necessary to alert doctors and investors that there may be significant hidden risks that could jeopardize the vision of the patients and otherwise make Defendants' statements not materially misleading.

| | Pegcetacoplan monthly | Pegcetacoplan every other month | Sham |
|---|---|---|---|
| **Monocular maximum reading speed** | | | |
| Patients included in the model* | 347/403 (86%) | 344/406 (85%) | 345/402 (86%) |
| Least-squares mean change (SE), words per min† | −22·49 (2·57) | −21·35 (2·16) | −19·13 (2·40) |
| Difference (95% CI) in least-squares mean pegcetacoplan *vs* sham, words per min | −3·36 (−9·89 to 3·17) | −2·23 (−8·20 to 3·75) | NA |
| p value pegcetacoplan *vs* sham | 0·31 | 0·47 | NA |
| **Functional reading independence index score** | | | |
| Patients included in the model‡ | 371/403 (92%) | 376/406 (93%) | 373/402 (93%) |
| Least-squares mean change (SE), score | −0·35 (0·04) | −0·37 (0·04) | −0·32 (0·04) |
| Difference (95% CI) in least-squares mean pegcetacoplan *vs* sham, score | −0·03 (−0·14 to 0·08) | −0·06 (−0·16 to 0·05) | NA |
| p value pegcetacoplan *vs* sham | 0·58 | 0·30 | NA |
| **Normal-luminance best-corrected visual acuity score** | | | |
| Patients included in the model§ | 403/403 (100%) | 406/406 (100%) | 402/402 (100%) |
| Least-squares mean change (SE), ETDRS letters | −7·89 (0·74) | −8·83 (0·74) | −6·94 (0·74) |
| Difference (95% CI) in least-squares mean pegcetacoplan *vs* sham, ETDRS letters | −0·95 (−2·97 to 1·07) | −1·89 (−3·93 to 0·15) | NA |
| p value pegcetacoplan *vs* sham | 0·36 | 0·069 | NA |
| **National Eye Institute Visual Functioning Questionnaire 25 distance activity subscale score** | | | |
| Patients included in the model¶ | 375/403 (93%) | 380/406 (94%) | 377/402 (94%) |
| Least-squares mean change (SE), score | −10·98 (1·35) | −10·10 (1·26) | −9·93 (1·19) |
| Difference (95% CI) in least-squares mean pegcetacoplan *vs* sham, score | −1·05 (−4·35 to 2·25) | −0·17 (−3·35 to 3·00) | NA |
| p value pegcetacoplan *vs* sham | 0·53 | 0·92 | NA |
| **Mean threshold macular sensitivity** | | | |
| Patients included in the model‖ | 179/202 (89%) | 187/205 (91%) | 186/207 (90%) |
| Least-squares mean change (SE), decibel | −3·32 (0·30) | −3·06 (0·23) | −2·95 (0·22) |
| Difference (95% CI) in least-squares mean pegcetacoplan *vs* sham, decibel | −0·37 (−1·06 to 0·33) | −0·11 (−0·69 to 0·47) | NA |
| p value pegcetacoplan *vs* sham | 0·30 | 0·71 | NA |

Data are n/N (%), unless otherwise stated. Secondary endpoints were analysed in OAKS and DERBY combined, except for the macular sensitivity measurement, which was only evaluated in OAKS. ETDRS=Early Treatment Diabetic Retinopathy Study. NA=not applicable. *Detailed information of the model is given in appendix 1 (p 11). †Maximum reading speed was calculated as the mean of the three highest non-zero reading speeds (or two, or one value, as available), except when all three reading speed values were 0, in which case the maximum reading speed was set at 0. ‡Detailed information of the model is given in appendix 1 (p 11). §Detailed information of the model is given in appendix 1 (p 11). ¶Detailed information of the model is given in appendix 1 (p 11). ‖Detailed information of the model is given in appendix 1 (p 11).

***Table 3:*** **Visual function endpoint results from baseline to month 24**

| Summary of Functional Outcomes Compared to Sham | Monthly | EOM |
|---|---|---|
| Vision | -13.7% | -27.2% |
| Max Reading Speed | -17.6% | -11.6% |
| Fx Reading Independence Score | -9.4% | -15.6% |
| NEI VFX-25 | -10.6% | -1.7% |
| Mac Sensitivity | -12.5% | -3.7% |

71. Defendants' statistical model operated on the false assumption that data was missing at random, which resulted in the model generating a misleading reduction rate (garbage in – garbage out). In reality, data was missing because there were significantly different dropout rates among the treatment (~30%) arm and the sham (~20%) arm. Yet, despite numerous requests from medical professionals, academics and others, Defendants failed to provide the necessary baseline data of those lost to follow-up, discontinued treatment or converted to wet AMD. By omitting this critical data when discussing the test results, Defendants were able to ensure their deception went undetected.

72. In fact, the studies overestimated treatment effects for several reasons.

a. First, one in three patients discontinued treatment prior to the conclusion of the study. A higher dropout rate in the treatment arm than in the sham arm improperly biases the treatment arm results because dropout rates are typically higher among those who either see no benefit or suffer side effects from the treatment. The resulting population that remains is thus a biased sample comprised of people who did better in the drug group compared to the sham.

b. Second, three times as many patients converted to exudative AMD in the treatment arm. This is significant because exudative AMD leads to artificially reduced dark areas in autofluorescence, which could incorrectly be interpreted as an improvement for the patient. Wet AMD was higher in the treatment arm thereby "reducing" the area of the lesions in

the treatment group compared to the control group but such reduction is not an improvement for the patient.

73. According to Dr. Vavvas, having such a high incompletion (or dropout) rate – almost one in three patients in one study and almost 1 in five patients in the other study – affects the true assessment not only of efficacy but also of safety and risk. Defendants did not disclose critical information about the dropouts necessary to make their statements not materially misleading. For example, Defendants failed to disclose the dropouts baseline risk characteristics, which impact efficacy assessment. But most importantly Defendants failed to disclose crucial and detailed information about the dropout's vision, complaints and clinical exam just prior to the last dose and afterwards.

74. Moreover, Dr. Vavvas explained that although Apellis would purportedly perform an angiogram at the conclusion of the study or in instances of early termination, in which case the protocol required that it be performed after a minimum of 30 days. This significant delay decreased the sensitivity of identifying the problems that led to early termination, as the problem may have been treated or resolved due to the passage of time.

75. According to Dr. Vavvas, based on the instances of inflammation, ischemic optic neuropathy, the dropout rates, and the Company's failure to instigate a defined protocol in either the OAKS or DERBY studies to promptly obtain angiography in cases of intraocular inflammation or ischemic optic neuropathy "management/CEO/the Company had to have known there was a real risk of vasculitis, which should have been disclosed." At best, Defendants recklessly disregarded the risk.

**E. Defendants' False and Misleading Statements**

76. The Class Period begins on January 28, 2021. On that day, Defendants held Apellis's Virtual Investor Event at which the Company gave an online presentation titled,

"Pegcetacoplan: Advancing the First Potential Treatment for Geographic Atrophy (GA)." In their presentation, Apellis touted the efficacy of using pegcetacoplan in patients with GA, including that the concluded "Phase 2 FILLY study met [its] primary endpoint, reducing GA lesion growth." Likewise, in reporting on expectations for the Phase 3 DERBY and OAKS trials, the Company represented that the DERBY and OAKS trials would improve upon the robust FILLY trial with "[t]op-line results expected Q3 2021."

77. On September 9, 2021, the Company announced top-line data for the DERBY and OAKS trials after a 12-month period. Among other things, Apellis noted that "[p]egcetacoplan was well tolerated in both Phase 3 studies." Critically, the Company also reported that "[n]o events of retinal vasculitis or retinal vein occlusion were observed" and that "[t]here were no clinically relevant changes in vision for patients who developed infectious endophthalmitis or intraocular inflammation."

78. On October 11, 2021, Apellis published a presentation titled, "Safety of intravitreal pegcetacoplan in geographic atrophy: results from the DERBY and OAKS trials." In connection with this presentation, Apellis represented that there "were no cases of vasculitis or occlusive vasculitis" to date in the OAKS and DERBY trials.

79. The above statements identified in ¶¶76-78 were materially false and misleading because Defendants misrepresented and failed to disclose the true risk that the use of SYFOVRE was associated with retinal vasculitis, despite knowing or recklessly disregarding that: (i) the rates of inflammation and neuropathy (symptoms of possible retinal vasculitis) in the OAKS and DERBY trials were similar to other intravitreal injection treatments where retinal vasculitis was found, (ii) the intravitreal injections utilized to administer SYFOVRE had an inherent risk of causing retinal vasculitis, (iii) there had been recent, high profile examples of intravitreal injections

causing retinal vasculitis, and (iv) the dropout rates in the treatment arms were significantly higher than in the sham arm indicating that there was a potential that side effects such as retinal vasculitis could have been causing participants to leave the trial. Indeed, even though Defendants understood that angiography was the proper method for determining the existence of retinal vasculitis, Defendants failed to create a defined protocol to promptly obtain angiography for the detection of retinal vasculitis in cases of intraocular inflammation or ischemic optic neuropathy.

80. Likewise, on November 8, 2021, Apellis discussed results for the DERBY and OAKS trials in its Form 10-Q quarterly report for the quarter ending September 30, 2021. Among other things, Apellis once again reported that "[n]o events of retinal vasculitis or retinal vein occlusion were observed" to date in the DERBY and OAKS trials. The Company also stated that "[t]here were no clinically relevant changes in vision for patients who developed infectious endophthalmitis or intraocular inflammation."

81. The above statements identified in ¶80 were materially false and misleading because Defendants misrepresented and failed to disclose the true risk that the use of SYFOVRE was associated with retinal vasculitis, despite knowing or recklessly disregarding that: (i) the rates of inflammation and neuropathy (symptoms of possible retinal vasculitis) in the OAKS and DERBY trials were similar to other intravitreal injection treatments where retinal vasculitis was found, (ii) the intravitreal injections utilized to administer SYFOVRE had an inherent risk of causing retinal vasculitis, (iii) there had been recent, high profile examples of intravitreal injections causing retinal vasculitis, and (iv) the dropout rates in the treatment arms were significantly higher than in the sham arm indicating that there was a potential that side effects such as retinal vasculitis could have been causing participants to leave the trial. Indeed, even though Defendants understood that angiography was the proper method for determining the existence of retinal vasculitis,

Defendants failed to create a defined protocol to promptly obtain angiography for the detection of retinal vasculitis in cases of intraocular inflammation or ischemic optic neuropathy.

82. On November 12, 2021, Apellis published a presentation titled "Treatment of Geographic Atrophy Secondary to Age-Related Macular Degeneration With Pegcetacoplan: Updates on the Randomized Phase 3 DERBY and OAKS Trials." In the presentation, the Company again touted the safety of SYFOVRE, noting that "[t]here were no cases of vasculitis or occlusive vasculitis."

83. The above statements identified in ¶82 were materially false and misleading because Defendants misrepresented and failed to disclose the true risk that the use of SYFOVRE was associated with retinal vasculitis, despite knowing or recklessly disregarding that: (i) the rates of inflammation and neuropathy (symptoms of possible retinal vasculitis) in the OAKS and DERBY trials were similar to other intravitreal injection treatments where retinal vasculitis was found, (ii) the intravitreal injections utilized to administer SYFOVRE had an inherent risk of causing retinal vasculitis, (iii) there had been recent, high profile examples of intravitreal injections causing retinal vasculitis, and (iv) the dropout rates in the treatment arms were significantly higher than in the sham arm indicating that there was a potential that side effects such as retinal vasculitis could have been causing participants to leave the trial. Indeed, even though Defendants understood that angiography was the proper method for determining the existence of retinal vasculitis, Defendants failed to create a defined protocol to promptly obtain angiography for the detection of retinal vasculitis in cases of intraocular inflammation or ischemic optic neuropathy.

84. On February 28, 2022, the Company filed its annual report for the fiscal year ended December 31, 2021, on Form 10-K. In the annual report, Apellis again stated that "[n]o events of retinal vasculitis or retinal vein occlusion were observed" in the DERBY and OAKS

trials and that "[t]here were no clinically relevant changes in vision for patients who developed infectious endophthalmitis or intraocular inflammation."

85. The above statements identified in ¶84 were materially false and misleading because Defendants misrepresented and failed to disclose the true risk that the use of SYFOVRE was associated with retinal vasculitis, despite knowing or recklessly disregarding that: (i) the rates of inflammation and neuropathy (symptoms of possible retinal vasculitis) in the OAKS and DERBY trials were similar to other intravitreal injection treatments where retinal vasculitis was found, (ii) the intravitreal injections utilized to administer SYFOVRE had an inherent risk of causing retinal vasculitis, (iii) there had been recent, high profile examples of intravitreal injections causing retinal vasculitis, and (iv) the dropout rates in the treatment arms were significantly higher than in the sham arm indicating that there was a potential that side effects such as retinal vasculitis could have been causing participants to leave the trial. Indeed, even though Defendants understood that angiography was the proper method for determining the existence of retinal vasculitis, Defendants failed to create a defined protocol to promptly obtain angiography for the detection of retinal vasculitis in cases of intraocular inflammation or ischemic optic neuropathy.

86. On March 16, 2022, the Company announced longer-term data from its Phase 3 DERBY and OAKS trials and again touted "that intravitreal pegcetacoplan continued to reduce geographic atrophy, or GA, lesion growth and demonstrated a favorable safety profile at month 18 for the treatment of GA secondary to age-related macular degeneration, or AMD." Apellis also assured investors that "[n]o events of retinal vasculitis or retinal vein occlusion were observed."

87. The above statements identified in ¶86 were materially false and misleading because Defendants misrepresented and failed to disclose the true risk that the use of SYFOVRE was associated with retinal vasculitis, despite knowing or recklessly disregarding that: (i) the rates

of inflammation and neuropathy (symptoms of possible retinal vasculitis) in the OAKS and DERBY trials were similar to other intravitreal injection treatments where retinal vasculitis was found, (ii) the intravitreal injections utilized to administer SYFOVRE had an inherent risk of causing retinal vasculitis, (iii) there had been recent, high profile examples of intravitreal injections causing retinal vasculitis, and (iv) the dropout rates in the treatment arms were significantly higher than in the sham arm indicating that there was a potential that side effects such as retinal vasculitis could have been causing participants to leave the trial. Indeed, even though Defendants understood that angiography was the proper method for determining the existence of retinal vasculitis, Defendants failed to create a defined protocol to promptly obtain angiography for the detection of retinal vasculitis in cases of intraocular inflammation or ischemic optic neuropathy.

88. Two months later, on May 2, 2022, the Company published a presentation titled, "Efficacy of intravitreal pegcetacoplan in patients with geographic atrophy (GA): 18-month results from the phase 3 OAKS and DERBY studies." In the presentation, Apellis again stated that "no cases of retinitis or vasculitis (occlusive or nonocclusive) were reported."

89. The above statements identified in ¶88 were materially false and misleading because Defendants misrepresented and failed to disclose the true risk that the use of SYFOVRE was associated with retinal vasculitis, despite knowing or recklessly disregarding that: (i) the rates of inflammation and neuropathy (symptoms of possible retinal vasculitis) in the OAKS and DERBY trials were similar to other intravitreal injection treatments where retinal vasculitis was found, (ii) the intravitreal injections utilized to administer SYFOVRE had an inherent risk of causing retinal vasculitis, (iii) there had been recent, high profile examples of intravitreal injections causing retinal vasculitis, and (iv) the dropout rates in the treatment arms were significantly higher than in the sham arm indicating that there was a potential that side effects such as retinal vasculitis

could have been causing participants to leave the trial. Indeed, even though Defendants understood that angiography was the proper method for determining the existence of retinal vasculitis, Defendants failed to create a defined protocol to promptly obtain angiography for the detection of retinal vasculitis in cases of intraocular inflammation or ischemic optic neuropathy.

90. On July 14, 2022, Apellis published a follow-up presentation titled, "Safety of Intravitreal Pegcetacoplan for Geographic Atrophy (GA): 18-Month Results from the DERBY and OAKS trials," and reported that "[p]egcetacoplan was well tolerated through Month 18" of the studies and that, out of the occurrences of patients experiencing intraocular inflammation, there were "[n]o reports of retinitis or vasculitis (occlusive or non-occlusive)."

91. The above statements identified in ¶90 were materially false and misleading because Defendants misrepresented and failed to disclose the true risk that the use of SYFOVRE was associated with retinal vasculitis, despite knowing or recklessly disregarding that: (i) the rates of inflammation and neuropathy (symptoms of possible retinal vasculitis) in the OAKS and DERBY trials were similar to other intravitreal injection treatments where retinal vasculitis was found, (ii) the intravitreal injections utilized to administer SYFOVRE had an inherent risk of causing retinal vasculitis, (iii) there had been recent, high profile examples of intravitreal injections causing retinal vasculitis, and (iv) the dropout rates in the treatment arms were significantly higher than in the sham arm indicating that there was a potential that side effects such as retinal vasculitis could have been causing participants to leave the trial. Indeed, even though Defendants understood that angiography was the proper method for determining the existence of retinal vasculitis, Defendants failed to create a defined protocol to promptly obtain angiography for the detection of retinal vasculitis in cases of intraocular inflammation or ischemic optic neuropathy.

92. On August 8, 2022, Apellis filed its Form 10-Q quarterly report for the quarter ended June 30, 2022. In the quarterly report, the Company reiterated that, "[a]t month 18, pegcetacoplan continued to demonstrate a favorable safety profile, consistent with safety at 12 months and longer-term exposure to intravitreal injections." Critically, Apellis also represented that "[n]o events of retinal vasculitis or retinal vein occlusion were observed."

93. The above statements identified in ¶92 were materially false and misleading because Defendants misrepresented and failed to disclose the true risk that the use of SYFOVRE was associated with retinal vasculitis, despite knowing or recklessly disregarding that: (i) the rates of inflammation and neuropathy (symptoms of possible retinal vasculitis) in the OAKS and DERBY trials were similar to other intravitreal injection treatments where retinal vasculitis was found, (ii) the intravitreal injections utilized to administer SYFOVRE had an inherent risk of causing retinal vasculitis, (iii) there had been recent, high profile examples of intravitreal injections causing retinal vasculitis, and (iv) the dropout rates in the treatment arms were significantly higher than in the sham arm indicating that there was a potential that side effects such as retinal vasculitis could have been causing participants to leave the trial. Indeed, even though Defendants understood that angiography was the proper method for determining the existence of retinal vasculitis, Defendants failed to create a defined protocol to promptly obtain angiography for the detection of retinal vasculitis in cases of intraocular inflammation or ischemic optic neuropathy.

94. Then, on August 24, 2022, the Company announced top-line data for the DERBY and OAKS trials after a 24-month period. Among other things, Apellis noted that "[p]egcetacoplan continued to demonstrate a favorable safety profile, consistent with safety data to date and longer-term exposure to intravitreal injections." Again, Apellis also stated that "[n]o events of occlusive vasculitis or retinitis were observed over 24 months."

95. The above statements identified in ¶94 were materially false and misleading because Defendants misrepresented and failed to disclose the true risk that the use of SYFOVRE was associated with retinal vasculitis, despite knowing or recklessly disregarding that: (i) the rates of inflammation and neuropathy (symptoms of possible retinal vasculitis) in the OAKS and DERBY trials were similar to other intravitreal injection treatments where retinal vasculitis was found, (ii) the intravitreal injections utilized to administer SYFOVRE had an inherent risk of causing retinal vasculitis, (iii) there had been recent, high profile examples of intravitreal injections causing retinal vasculitis, and (iv) the dropout rates in the treatment arms were significantly higher than in the sham arm indicating that there was a potential that side effects such as retinal vasculitis could have been causing participants to leave the trial. Indeed, even though Defendants understood that angiography was the proper method for determining the existence of retinal vasculitis, Defendants failed to create a defined protocol to promptly obtain angiography for the detection of retinal vasculitis in cases of intraocular inflammation or ischemic optic neuropathy.

96. On a conference call discussing the 24-month results for the Phase 3 DERBY and OAKS trial on August 24, 2022, Defendant Francois reiterated that the results continued to show "a favorable safety profile in line with what we saw at 12 and 18 months."

97. The above statements identified in ¶96 were materially false and misleading because Defendants misrepresented and failed to disclose the true risk that the use of SYFOVRE was associated with retinal vasculitis, despite knowing or recklessly disregarding that: (i) the rates of inflammation and neuropathy (symptoms of possible retinal vasculitis) in the OAKS and DERBY trials were similar to other intravitreal injection treatments where retinal vasculitis was found, (ii) the intravitreal injections utilized to administer SYFOVRE had an inherent risk of causing retinal vasculitis, (iii) there had been recent, high profile examples of intravitreal injections

causing retinal vasculitis, and (iv) the dropout rates in the treatment arms were significantly higher than in the sham arm indicating that there was a potential that side effects such as retinal vasculitis could have been causing participants to leave the trial. Indeed, even though Defendants understood that angiography was the proper method for determining the existence of retinal vasculitis, Defendants failed to create a defined protocol to promptly obtain angiography for the detection of retinal vasculitis in cases of intraocular inflammation or ischemic optic neuropathy.

98. On November 3, 2022, Apellis published an updated presentation titled, "Safety of intravitreal pegcetacoplan in geographic atrophy: 24-month results from the OAKS and DERBY phase 3 trials." The Company again reported "[n]o reports of occlusive or nonocclusive retinitis or vasculitis."

99. The above statements identified in ¶98 were materially false and misleading because Defendants misrepresented and failed to disclose the true risk that the use of SYFOVRE was associated with retinal vasculitis, despite knowing or recklessly disregarding that: (i) the rates of inflammation and neuropathy (symptoms of possible retinal vasculitis) in the OAKS and DERBY trials were similar to other intravitreal injection treatments where retinal vasculitis was found, (ii) the intravitreal injections utilized to administer SYFOVRE had an inherent risk of causing retinal vasculitis, (iii) there had been recent, high profile examples of intravitreal injections causing retinal vasculitis, and (iv) the dropout rates in the treatment arms were significantly higher than in the sham arm indicating that there was a potential that side effects such as retinal vasculitis could have been causing participants to leave the trial. Indeed, even though Defendants understood that angiography was the proper method for determining the existence of retinal vasculitis, Defendants failed to create a defined protocol to promptly obtain angiography for the detection of retinal vasculitis in cases of intraocular inflammation or ischemic optic neuropathy.

100. During the "5th Annual Evercore ISI HealthCONx Conference 2022" on November 29, 2022, in response to a participant's question that, "to date, no vasculitis or retinitis" had been observed, Defendant Francois confirmed, "[t]hat is correct."

101. The above statements identified in ¶100 were materially false and misleading because Defendants misrepresented and failed to disclose the true risk that the use of SYFOVRE was associated with retinal vasculitis, despite knowing or recklessly disregarding that: (i) the rates of inflammation and neuropathy (symptoms of possible retinal vasculitis) in the OAKS and DERBY trials were similar to other intravitreal injection treatments where retinal vasculitis was found, (ii) the intravitreal injections utilized to administer SYFOVRE had an inherent risk of causing retinal vasculitis, (iii) there had been recent, high profile examples of intravitreal injections causing retinal vasculitis, and (iv) the dropout rates in the treatment arms were significantly higher than in the sham arm indicating that there was a potential that side effects such as retinal vasculitis could have been causing participants to leave the trial. Indeed, even though Defendants understood that angiography was the proper method for determining the existence of retinal vasculitis, Defendants failed to create a defined protocol to promptly obtain angiography for the detection of retinal vasculitis in cases of intraocular inflammation or ischemic optic neuropathy.

102. On February 17, 2023, Apellis issued a press release announcing the FDA approval of pegcetacoplan injections for the treatment of GA under the name SYFOVRE. The press release identified the following "WARNINGS AND PRECAUTIONS," related to SYFOVRE: (1) "Endophthalmitis and Retinal Detachments," (2) "Neovascular AMD," (3) "Intraocular inflammation," and (4) "Increased Intraocular Pressure." Notably absent from the warning was the risk of vasculitis.

103. The above statements identified in ¶102 were materially false and misleading because Defendants misrepresented and failed to disclose the true risk that the use of SYFOVRE was associated with retinal vasculitis, despite knowing or recklessly disregarding that: (i) the rates of inflammation and neuropathy (symptoms of possible retinal vasculitis) in the OAKS and DERBY trials were similar to other intravitreal injection treatments where retinal vasculitis was found, (ii) the intravitreal injections utilized to administer SYFOVRE had an inherent risk of causing retinal vasculitis, (iii) there had been recent, high profile examples of intravitreal injections causing retinal vasculitis, and (iv) the dropout rates in the treatment arms were significantly higher than in the sham arm indicating that there was a potential that side effects such as retinal vasculitis could have been causing participants to leave the trial. Indeed, even though Defendants understood that angiography was the proper method for determining the existence of retinal vasculitis, Defendants failed to create a defined protocol to promptly obtain angiography for the detection of retinal vasculitis in cases of intraocular inflammation or ischemic optic neuropathy.

104. On February 17, 2023, Apellis held a conference call discussing the FDA approval of pegcetacoplan injections for the treatment of GA under the name SYFOVRE. In the presentation accompanying the call, the Company touted SYFOVRE as "[t]he **first and only** FDA approved treatment for geographic atrophy secondary to age-related macular degeneration." The Company also represented that SYFOVRE showed a "[w]ell-demonstrated safety profile" following approximately 12,000 injections over a 24-month period. Moreover, the Company again highlighted that "**[n]o events** of occlusive or non-occlusive vasculitis or retinitis were observed" during the DERBY and OAKS trials.

105. The above statements identified in ¶104 were materially false and misleading because Defendants misrepresented and failed to disclose the true risk that the use of SYFOVRE

was associated with retinal vasculitis, despite knowing or recklessly disregarding that: (i) the rates of inflammation and neuropathy (symptoms of possible retinal vasculitis) in the OAKS and DERBY trials were similar to other intravitreal injection treatments where retinal vasculitis was found, (ii) the intravitreal injections utilized to administer SYFOVRE had an inherent risk of causing retinal vasculitis, (iii) there had been recent, high profile examples of intravitreal injections causing retinal vasculitis, and (iv) the dropout rates in the treatment arms were significantly higher than in the sham arm indicating that there was a potential that side effects such as retinal vasculitis could have been causing participants to leave the trial. Indeed, even though Defendants understood that angiography was the proper method for determining the existence of retinal vasculitis, Defendants failed to create a defined protocol to promptly obtain angiography for the detection of retinal vasculitis in cases of intraocular inflammation or ischemic optic neuropathy.

106. On February 21, 2023, the Company filed its annual report for the fiscal year ended December 31, 2022, on Form 10-K. In the annual report, Apellis again stated that "SYFOVRE was well-tolerated in both DERBY and OAKS" and that "[n]o events of occlusive or non-occlusive vasculitis or retinitis occlusion were observed over 24 months" in the DERBY and OAKS trials.

107. The above statements identified in ¶106 were materially false and misleading because Defendants misrepresented and failed to disclose the true risk that the use of SYFOVRE was associated with retinal vasculitis, despite knowing or recklessly disregarding that: (i) the rates of inflammation and neuropathy (symptoms of possible retinal vasculitis) in the OAKS and DERBY trials were similar to other intravitreal injection treatments where retinal vasculitis was found, (ii) the intravitreal injections utilized to administer SYFOVRE had an inherent risk of causing retinal vasculitis, (iii) there had been recent, high profile examples of intravitreal injections causing retinal vasculitis, and (iv) the dropout rates in the treatment arms were significantly higher

than in the sham arm indicating that there was a potential that side effects such as retinal vasculitis could have been causing participants to leave the trial. Indeed, even though Defendants understood that angiography was the proper method for determining the existence of retinal vasculitis, Defendants failed to create a defined protocol to promptly obtain angiography for the detection of retinal vasculitis in cases of intraocular inflammation or ischemic optic neuropathy.

**F. The Truth Begins to Emerge As Defendants Continue to Mislead Investors**

108. After more than two years of repeatedly hearing from Defendants – more than a dozen times – that there were no reported cases of vasculitis or retinitis, the market began to learn otherwise. On Saturday July 15, 2023, the American Society of Retina Specialist Research and Safety in Therapeutics ("ASRS ReST") Committee issued a notice reporting occurrences of retinal vasculitis in patients receiving SYFOVRE treatment. Specifically, the ASRS ReST Committee indicated that ophthalmologists had observed six instances of retinal vasculitis following SYFOVRE treatments.

109. On this news, the price of Apellis common stock declined $32.04 per share, or approximately 38%, from a close of $84.50 per share on Friday July 14, 2023, to close at $52.46 per share on Monday July 17, 2023.

110. Then, after the market closed on July 17, 2023, the Company issued a statement addressing the concerns raised by ASRS regarding vasculitis and SYFOVRE, explaining that:

> All events were observed after the first injection of SYFOVRE, between 7-13 days after drug administration, and with no specific lots implicated. Upon review with external experts, two of the events were confirmed as occlusive, one was confirmed as non-occlusive, and the remaining three were undetermined based on limited information and lack of imaging. The etiology of these events is unclear, and outcomes in these patients are still evolving.

* * *

> The Company is continuing to conduct a thorough investigation of each of the events, working closely with the ReST Committee and several external specialists. Apellis takes adverse event reporting very seriously and immediately followed up with the FDA upon receiving the reports of vasculitis. In this regard, each event was reviewed with the FDA and no action is planned at this time. The Company has updated ReST on these interactions and will continue to do so should new information become available.

111. On this news, the price of Apellis common stock declined $12.46 per share, or 23.75%, from a close of $52.46 per share on July 17, 2023, to close at $40.00 per share on July 18, 2023.

112. Prior to the open of market hours on July 20, 2023, given the recently disclosed vasculitis risks, Wedbush downgraded Apellis's price target by more than 50%, from $86.00 per share, to $40.00 per share.

113. On this news, the price of Apellis common stock declined $6.25 per share, or approximately 15%, from a close of $40.49 per share on July 19, 2023, to close at $34.24 per share on July 20, 2023.

114. On July 29, 2023, Apellis issued a press release providing an update on the Company's review of the six events of retinal vasculitis reported by the ASRS concerning SYFOVRE treatments. In the update, Apellis confirmed a seventh event of retinal vasculitis resulting from SYFOVRE treatment as determined by Apellis' internal safety committee and external retina/uveitis specialists. Additionally, Apellis stated that the Company is evaluating an eighth reported event of retinal vasculitis, which the Company had not yet confirmed.

115. On this news, the price of Apellis common stock declined $6.27 per share, or approximately 19.6%, from a close of $32.02 per share on July 28, 2023, to close at $25.75 per share on July 31, 2023.

116. In November 2023, SYFOVRE's prescribing information was updated to include "Retinal Vasculitis and/or Retinal Vascular Occlusion" under "Warnings and Precautions."

117. Importantly, on December 21, 2023, ASRS ReST Committee published a further review of the instances of vasculitis caused by SYFOVRE, highlighting that while "[t]here were no reported cases of retinal vasculitis or occlusive retinal vasculopathy in the clinical trials. Notably, however, there was no defined protocol in these studies to obtain angiography in cases of intraocular inflammation."

### G. Additional Allegations of Scienter

#### 1. Defendants' Baseless Assertions of Other Reasons for The Vasculitis Supports an Inference of Scienter

118. Defendants' scienter is further demonstrated by their attempt to mislead investors as to the cause of vasculitis even after it was disclosed by the ASRS. For example, immediately after the first disclosure that vasculitis was associated with the use of SYFOVRE, Defendant Francois baselessly provided numerous non-SYFOVRE explanations, claiming that it could not be SYFOVRE and doubling down on Defendants' prior representations that they did not observe any instances of vasculitis during the clinical studies. Yet, Defendants continued to mislead investors by failing to disclose that Apellis had no defined protocol in either the OAKS or DERBY studies to promptly obtain angiography in cases of intraocular inflammation or ischemic optic neuropathy, which could detect vasculitis.

119. Investors continued to be misled by Defendants' denials. As a UBS analyst observed in a July 18, 2023 report: "management believes the reported vasculitis cases could be mis-diagnosed cases of infectious endophthalmitis."

120. Defendants then continued to mislead the market by providing different excuses to other analysts. As a BofA Securities analyst noted in a July 17, 2023 report: "We spoke with

mgmt this morning and highlight…the company at this time doesn't believe the effects are related to the drug itself but rather could be related to procedures themselves (mixing the contents of the injection, using proper sterility." The analysts believed Defendants' baseless assertions because they continued to believe their prior misleading statements about the clinical studies: "We think that lack of such observations in clinical studies lends credence to the events being impacted by procedures used to prep injections for use."

121. A JP Morgan analyst was similarly misled and observed in a July 17, 2023 report: "Net-net, we see the ASRS as more of a prudent reminder to physicians to use guidelines / safety monitoring versus a major safety concern emerging."

122. And a TD Cowen analyst wrote in a July 17, 2023 report:

> The KOL believes that the risk of retinal vasculitis is elevated by SYFOVRE treatment. His initial guess is that the cause is associated with manufacturing or delivery, not the mechanism of C3 inhibition. He thinks the issue is unlikely to be related to SYFOVRE's mechanism because vasculitis was not seen in SYFOVRE's clinical trials… He suspects it could be due to changes in the manufacturing process from the clinical to the commercial, or due to the delivery of SYFOVRE by physicians with poor technique… He suggests it is also possible some physicians could be incorrectly drawing the SYFOVRE from the vial, using substituted syringes and materials, or employing some other flawed technique.

123. The most prominent of these false explanations provided by Defendants was that vasculitis was somehow related to the needle used to filter SYFOVRE from the vial – not the needle used to inject it into the patient's eye. Defendant Francois stated that the kits provided to physicians contained either a 19-gauge filter needle or and 18-gauge filter needle. Critically, Apellis knew that vasculitis had occurred in the use of each type of needle. Nevertheless, the Company quickly began a media blitz misleadingly suggesting that the 19-gauge filter needle and the instances of vasculitis could be connected when they knew they were not.

124. For example, the headline of an August 22, 2023 press release stated: "Apellis Provides Updates on Injection Kits and Rare Safety Events with SYFOVRE." The press release continued:

> As part of the comprehensive investigation into the real-world safety events, internal structural variations were identified in the specific 19-gauge x 1½ inch filter needle included in certain injection kits…The Company recommends that practitioners immediately discontinue use of any injection kits that contain the 19-gauge filter needle and use injection kits with the 18-gauge filter needle, which are already in distribution..."Based on the findings from our investigation, we believe it is prudent that practitioners only use the kits with the 18-gauge filter needle, which are already in distribution. This recommendation is out of an abundance of caution as patient safety is our top priority," said Caroline Baumal, M.D., chief medical officer of Apellis… "To date, more than 100,000 vials have been distributed for commercial use and for administration in clinical trials, and the events of retinal vasculitis continue to be very rare at an estimated real-world rate of 0.01% per injection."

125. Francois went even further during a September 6, 2023, earnings call, falsely stating that the differences between the 19 gauge filter needle and what was used in the clinical studies were "important" differences "that may explain these cases of vasculitis":

> Cedric Francois - Apellis Pharmaceuticals, Inc. - Co-Founder, President, CEO & Director
>
> [W]hat was different between the clinical trials in the real world that may explain these cases of vasculitis. And one of the most important ones there was that in the clinical trial work to use something called a vial adapter, which is where you take the vial with SYFOVRE, you put an adaptor on it, and you suck the liquids through a filter that sits inside that vial, which is kind of a 3D construct in that filter.
>
> When we came on the market, we decided to provide ancillary kits with 2 types of filter needles. So filter needle is not a vial adapter, but something that you actually stick through the rubber and then pull it the liquids through the filter in that needle. We chose 2 needles to make sure that we could meet the incredible demand that there was. I mean, this was an amazingly rapid launch. And one of the important differences between these needles is beyond the size, of course, with 19-gauge being smaller compared to the 18-gauge and therefore, harder to pull the liquid up is that the filter material and the 19-gauge needle is made out of a monomeric nylon mesh, whereas the 18-gauge needle has a filter material that is identical to the one that sits in the vial adaptor.

126. In truth, both the 19-gauge needles and 18-gauge needles met the FDA specifications for administering SYFOVRE. Moreover, Defendant Francois knew that instances of vasculitis were associated with the 18-gauge needle as well, disproving any speculation that the 19-gauge needle was the cause.

127. Notably, Defendant Francois continued to mislead investors even when asked point-blank by an analyst from Citigroup Inc. – Yiga Dov Nochomovitz, "So of the 8 cases though, I don't think you've been able to identify which needles, they -- those patients had, right? Is that correct? Or were they known to be 19 or not?" Defendant Francois knew, or recklessly disregarded, that both needles had been associated with cases of vasculitis. Nevertheless, he stated:

> [T]he 19-gauge needle was the predominant needle that was on the market in the spring. Then you have many practices that have both needles sitting in their trees, right? And typically, the technicians or nurses or even the doctors that take these ancillary kits, they don't go checking for what needle is in there. They take it and it could be one or the other. So ***we have cases that were definitively linked to that 19-gauge needle***, and then we had sites where both were available.
>
> And when we did a probabilistic analysis, that is where it became quite striking that ***there was an association that was quite profound with a 19-gauge needle***.

128. Apellis even published a "sponsored" article – essentially a paid-for advertisement in the guise of a medical journal article – in Retina Today attempting to sell the public on the possible connection between the 19-gauge needle and vasculitis. Apellis continued to relate the 19-gauge needle as a possible causal relationship. The title of the article was "SYFOVRE: Insights on Case Reports of Retinal Vasculitis and Removal of 19-Gauge Filter Needle." The article continued to site wholly irrelevant facts to suggest that the 19-gauge needles, which were no longer being used, could be the cause of vasculitis, so as to regain patients.

> Zero cases of retinal vasculitis were identified in the clinical trials; thus, a critical focus of the investigation has been to analyze the differences between the real-world experience and the clinical trials with SYFOVRE. One notable difference is that in the clinical trials, a vial adapter with a 5-micron filter was used to extract SYFOVRE from the vial in which it was provided. For SYFOVRE commercial product, a filter needle was used as these are more commonly used with intravitreal injections…
>
> The 19-gauge filter needle contains a monofilament nylon, woven mesh filter. The 18-gauge filter needle has a three-dimensional, microscopically porous filter, which is the same filter material included in the vial adapter used in the clinical trials. Notably, the 18-gauge filter needle was also used with certain subjects during the early clinical trial experience.
>
> During the investigation of these two filter needles, Apellis found structural variations associated with the 19-gauge filter needle that caused concern. Specifically, the nylon mesh in certain 19-gauge filter needles had non-optimal features, such as double- or triple-packed filters, exposed filter material, or inadequate filter seams. These variations present a potential risk of device-related particulates inadvertently being introduced into the eye.

129. Defendants also attempted to keep the dangers of SYFOVRE off the analyst's headlines by repeating the false statistics of safety and stating that they would not know the results of discontinuing use of the 19-gauge needles for several more months.

130. Addressing the possible causes of the vasculitis during a September 6, 2023 earnings call, Defendant Francois stated, "We will only find out in the months to come." During a November 1, 2023 earnings call, Defendant Francois again stated "talking about etiology, so it is still too early, right? I mean, we're going to need probably another quarter or 2 to really understand whether the needle had an impact or not."

131. Despite Defendants' attempt to create a narrative to the contrary, SYFOVRE has continued to cause retinal vasculitis in patients well after the Company discontinued use of the 19-gauge filter needs.

**2. Defendants' Manipulation of Data Supports an Inference of Scienter**

132. After the instances of retinal vasculitis were revealed to the market, Defendants continued to mislead investors (and doctors and patients) about the risk by making repeated assurances that the risk of vasculitis was merely 1 in 10,000 so as to make it seem that the risk was similar to other intravitreal treatments. However, Defendants' justification for this figure was baseless and ever-shifting.

133. Apellis' July 17, 2023 SEC filing made immediately after the revelation of vasculitis stated compared the six instances of vasculitis to the 60,000 vials of SYFOVRE that had been distributed since approval:

> All events were observed after the first injection of SYFOVRE, between 7-13 days after drug administration…The reported vasculitis events have occurred at an estimated rate of approximately 1 in 10,000 injections, or 0.01% per injection. To date, approximately 60,000 vials of SYFOVRE have been distributed since the U.S. Food and Drug Administration ("FDA") approval on February 17, 2023.

134. This wildly under-estimates the risk of vasculitis. First, only a fraction of the 60,000 vials "distributed" as of the date of the SEC filing could have actually been used by physicians. Second, as Apellis acknowledged, "[a]ll events were observed after the first injection of SYFOVRE." Thus, the proper risk analysis would be the number of incidents of retinal vasculitis compared to the number of patients, not injections, and certainly not the number of vials distributed. By July 17, 2023, some patients could have received as many as ten injections (one injection in each eye every month for five months). Defendant Francois' purported risk 0.01% treats patients that had received an injection in each eye every month for five months – ten injections – as having an equal risk of retinal vasculitis with each shot. In reality, their risk after the first injection was closer to zero. Even if every single one of the 60,000 vials distributed had been used, they could have been used in only 6,000 patients, in which case the real risk of vasculitis would be as high as 1:1,000, not 1:10,000.

135. Nevertheless, analysts repeated Defendants' statistical manipulations, taking comfort in them to incorrectly conclude that the risk was not as significant as other cases involving similar drugs:

136. A July 17, 2023, BofA Securities analyst report stated: "~60K vials have been distributed since commercialization in Feb (6K vials in 1Q. This indicates to us that the vasculitis rate thus far is in line with historical experience." The report also stated: "We think today's stock reaction could have less to do with APLS' reported update and more to do with investors' previous experience with another drug for the eye (NVS' Beovu) which showed vasculitis side effect early in the launch which significantly impacted uptake. While we note that the vasculitis rate APLS is reporting thus far is lower, we think this now is an overhang pending additional color from the company. Pending additional updates, we maintain our Buy rating with $114 PO."

137. A July 17, 2023, Evercore ISI report similarly stated that the misleading risk ratio compared favorably to other situations in which higher rates significantly harmed the use of the treatment to the company's detriment:

> Post-marketing, Beovu had 9 in 10K injections had retinal artery occlusion, vasculitis or severe vision loss. APLS has 6 case of vasculitis in 60K vials (so even if 75% of vials used, that's 6 out of 45K injections = 1.3 in 10K injections)

138. A July 17, 2023, JP Morgan analyst report similarly observed: "we would note this not even close to rates of Beovu's retinal vasculitis and that low rates are common with other VEGFs"

139. A July 17, 2023 Oppenheimer analyst report stated: "As some may recall, Beovu's concerns were raised in the middle of its second quarter of launch (early 2020) on ultimately 11 cases of occlusive retinal vasculitis, which was elucidated as a rate of 9-10 rare events per 10,000, leading to ultimately a label warning by the summer and stalled commercial trajectory."

140. A July 17, 2023, TD Cowen analyst report stated: "It has been noted that there have been 6 cases and 60K SYFOVRE vials shipped, which would imply a 1:10,000 rate, in-line with the anticipated risk of endophthalmitis."

141. Defendants continued this pattern of misleading the public. By July 29, 2023, the number of confirmed cases of vasculitis had risen to seven. In a press release, Defendant Francois stated, "Following 68,000 commercial vials distributed and 23,000 clinical trial injections to date, these events continue to be very rare." Defendants increased the number of vials "distributed" from 60,000 to 68,000 based on shipments of vials since July 17, 2023 to maintain the 1:10,000 ratio even though Defendants knew that the newly-confirmed case of vasculitis had occurred in May 2023.

142. By August 22, 2023, the number of confirmed cases had increased to eight. Again, even taking Defendants at their word that the most recently confirmed case dated back to June 2023, Defendants continued to further inflate the denominator, asserting in a press release that "To date, more than 100,000 vials have been distributed for commercial use and for administration in clinical trials, and the events of retinal vasculitis continue to be very rare at an estimated real-world rate of 0.01% per injection."

143. As the number of instances of vasculitis increased to at least 12 even after Apellis ordered physicians to discontinue use of the 19-gauge filter needles, Defendants continued to manipulate the figures to falsely assert that the risk to patients was 1:10,000.

144. During a November 1, 2023 earnings call, Defendant Francois stated:

> [T]he most important metric here is that the rate of vasculitis is very low and stable, right, something that over the past couple of months, we've been able to track. And of course, it provides confidence to the physicians. So with more than 100,000 injections done in the real world, we are at a rate and continues to be at a rate of 0.01%.

145. Defendant Francois again improperly inflated the denominator to understate the risk of vasculitis. His ratio was based on the number of incidents of retinal vasculitis compared to the number of injections through November 1, 2023. First, as explained above, the proper denominator should have been the number of patients, not the number of injections. Second, the most recent case of vasculitis that the company had fully investigated and reported on was from September. Therefore, the proper denominator should have been the number of patients treated as of September, not November. Using the proper figures would have increased the risk of vasculitis to as high as 1:1,000, not 1:10,000.

146. Defendant Francois repeated the misleading 1 in 10,000 figure during a November 28, 2023 analyst call, specifically comparing it to a recent high profile case to highlight that patients, physicians and investors should be comforted by the figure.

> I think it's important to note here, this is so extremely rare on such a large denominator. It has to be placed in the context of the history, right? The problem was or if brolucizumab, i.e. Beovu had not happened a couple of years ago, this would never have been or turn into what it is today. That is just a simple fact. What happened back then is, it started off being a 1 in 10,000 event. But because patients were getting sensitized against that drug, it became more and more. And in the end, it was 150 subjects that have this. This is completely different.

147. Notably, when Francois was questioned by Jonathan Miller – Evercore ISI Institutional Equities, Research Division – "This is a first dose phenomenon and there's no acceleration, is the proper denominator total doses given or not new patients given...", Defendant Francois continued to mislead investor on multiple levels:

> No, I think that's an excellent point. So I think from either angle, right, it looks very good for us, right? So we have, on the last time that we updated this, we have -- more than 50,000 subjects that have at least received one injection. And we have well north of 100,000 injections at this point in time as well. If you take patients with bad visual outcomes, right, there were 5 patients with bad visual outcomes on a total of 50,000 subjects... There again, you have that very small number of cases as well. So on either way you look at it, it's something very rare sporadic. Physicians appreciate this now, and I think have largely moved beyond that and are now focused on efficacy, right…

148. First, the denominators – the 100,000 injection figure and 50,000 patients assumption – are incorrect because they are "at this point in time" instead of the point in time of the last fully analyzed case of vasculitis. Moreover, Francois assumed that over the eight months of treatment the 100,000 injections were distributed to 50,000 patients. That assumes that the average patient only received two injections over eight months. That's, on average, one injection in each eye over eight months. SYFOVRE was recommended to be used every month or every other month. In reality, certain patients would receive two injections during their first treatment (one in each eye), and patients continuing to use SYFOVRE would receive as many as two more each month.

149. Second, Francois changed the numerator from the number of instances of retinal vasculitis (more than 10) to the number of instances that also resulted in severe vision loss (about 5). By manipulating these figures, he misleadingly maintained that the risk was still 0.01%

### 3. Defendants' Experience with Intravitreal Injections and Related Safety Issues Supports an Inference of Scienter

150. Apellis has been conducting clinical trials of intravitreal pegcetacoplan for the treatment of geographic atrophy for ten years. In the course of those various trials, Defendants have had numerous meetings with the FDA and calls with analysts concerning the safety of those trials – the design of the trials as well as the results concerning safety.

151. Adverse events were not new to Defendants. Both the phase 2 study as well as the phase 3 studies had prior safety concerns, including related to inflammation. As Defendant Francois discussed during a January 9, 2019 call with investors:

> We had this manifestation of new onset exudations. And when we first saw this, this was a concern to us. This happened in the Phase II clinical trial. And what this is, is these are small cystoid changes in the retina that leak and need to be treated with anti-VEGF. Most of these came from those patients in our study that

at baseline had wet AMD already in their fellow eye and therefore, seem to be predisposed in the contralateral eye. Now these were the types of lesions that don't lead to significant vision loss, which is why the FDA in Phase III allowed us to make no changes to our patient population and move forward accordingly.

And then finally, our 2 Phase III clinical programs. We started these in September. Unfortunately, due to inflammation related to a manufacturing issue, we had to pause dosing in these studies, but we hope to resume that shortly.

152. During a September 10, 2020 investor call, a Citigroup Inc. analyst asked:

I guess the tougher question would be there's been obviously some controversy around the safety signal and specifically this -- some incidence of new onset choroidal neovascularization seen with -- in the FILLY trial that seem to be more prevalent in the active arms and more prevalent in the monthly arm versus the every-other-month arm. So I think it would be really helpful for us and for everyone listening if you could help put that in perspective: what does that really mean? How significant of an issue is that? I understand that the patients can be treated with anti-VEGF if they develop it. And I also understand that it was -- that, that signal was more prevalent in the patients that already had choroidal neovascularization in their fellow eye in the prior FILLY trial.

So really helpful for you to put that in perspective just to balance the risk associated with new onset CNV as well as the goal with the therapy to obviously delay progression.

Defendant Francois responded in detail:

Yes. Thank you very much, Yigal, for that question. And I want to start this discussion with the following: what we saw in the FILLY trial was not a safety concern. Full stop…

So why did the FDA not have a problem with this? Because what we saw in these patients were all -- none of the cases that we saw were classical CNV. And wet AMD is something that retinal specialists automatically associated with classical CNV. And what is classical CNV? it is new blood vessels that grow between the RPE and the retinal cell layer that leak very heavily. And if you do not treat that, these patients go blind with anti-VEGF, right? We had 0 cases. Not a single case of those out of the 26 cases of exudation that we saw in the FILLY clinical trial.

What we had in the FILLY clinical trial, and I want to stress this, is we had an imbalance in anti-VEGF treatment. That is what we had. We have more patients who were receiving anti-VEGF treatment in the monthly versus every-other-month versus the sham and what looked indeed like the perfect dose response. But the reason for that anti-VEGF treatment in which there was an investigator bias

> were small exudates that were perceived in the retina that were not threatening to vision and that, again, in not a single case were classical CNV.
>
> And you could say -- and we have hypotheses as to why the small exudates were seen, including the fact that many of these patients have preexisting CNV that doesn't leak and can become more leaky when repair mechanisms kick in because VEGF, even though you want to inhibit it in the context of leakage, is a repair signaling molecule as you know. So there's much more that we will learn from that. But the key message, which unfortunately has been misinterpreted for a long time now, is that this was never a safety concern, not for us and not for the FDA.

153. Moreover, Defendant Francois worked closely with consultants and doctors who understood the risk of vasculitis, and the need for heightened clinical attention to the potentially devastating adverse reaction. For instance, Jeffrey S. Heier ("Heier"), a partner of the Ophthalmic Consultants of Boston, Inc., explained at the January 28, 2021 Virtual Investor Event that he worked directly with Francois and Federico Grossi (Apellis's Chief Medical Officer) and the Apellis scientists for nearly 10 years, "so I've seen this program as it has progressed." He was also "the lead investigator on the DERBY study[.]" He notes that in the FILLY study, "there were 2 cases of endophthalmitis over roughly 1,500 injections, and this falls in line with what we have seen in other clinical trials." In his summary for the FILLY results, he reiterated: "safety is in line with other studies of intravitreally administered agents."

154. Mere months earlier, in November of 2020, Heier co-authored a journal article in the American Academy of Ophthalmology entitled, "Risk of Inflammation, Retinal Vasculitis, and Retinal Occlusion – Related Events with Brolucizumab" which, in its penultimate paragraph, advised: "Based on the findings of this analysis, we encourage vigilance in practice, with active surveillance and prompt reporting of cases of IOI, retinal vasculitis, and retinal occlusion. Routine monitoring should be more comprehensive than that typically performed in clinical practice, incorporating slit-lamp examination and ophthalmoscopy combined with fundus imaging (if inflammation is suspected)." The paragraph continues, "If inflammation is detected,

injections should cease, widefield [fluorescein angiography ("FA")] or FA with peripheral sweeps should be performed, and systemic and/or local corticosteroid treatment considered."

#### 4. Defendants' Detailed Discussions About Safety and Vasculitis Support an Inference of Scienter

155. Scienter is further supported by the fact that the Company's press releases and SEC filings, and the Defendants' statements and responses to questions on conference calls, as detailed above, all contained detailed, specific information about the subject matters of the alleged frauds, including the instances of inflammation, ischemic optic neuropathy, the risk of vasculitis, the dropout rates and the Apellis' failure to promptly perform an angiography in instances of inflammation or ischemic optic neuropathy. In drafting, reviewing or commenting on press releases and SEC filings, and preparing for conference calls and investor presentations - and making the specific representations that they made the Defendants either knew, or recklessly disregarded the facts underlying these matters.

156. In particular, despite no affirmative obligation to do so, in every instance that they reported on the phase 3 clinical studies, Defendants went out of their way to assure in investors "[n]o events of occlusive or non-occlusive vasculitis or retinitis occlusion were observed over 24 months" in the DERBY and OAKS trials.

#### 5. The Critical Importance of SYFOVRE to Apellis Supports an Inference of Scienter

157. Additionally, as set forth in detail herein, the frauds alleged relate to the core business and operations of Apellis. Specifically, at all times, SYFOVRE was Apellis's "lead product candidate" and its adoption by physicians after FDA approval was critical to Apellis's financial condition. The risk/benefit analysis to patients was directly connected to whether SYFOVRE would be adopted by the market and to what degree. Defendants and analysts regularly discussed these issues, which drove the financial projections for SYFOVRE and

Apellis. The launch of SYFOVRE was a watershed event in the evolution of the Company, as evidenced by Defendants' statements and the immense analyst focus on the topic. Accordingly, knowledge of the frauds may be imputed to Defendants.

158. Just before the Class Period began, at the January 12, 2021 JP Morgan Healthcare Conference, Defendant Francois explained that one of the Company's "key objective[s]" was "to be #1 in the retina." Defendant Francois discussed the then-forthcoming results of the Phase III clinical trials in geographic atrophy, which he said would be "the seminal and changing event for our company[.]"

159. At the Company's Virtual Investor Day on January 28, 2021, Defendant Francois again described the then-forthcoming DERBY and OAKS readouts as "a seminal event for our company," and "promise[d]" investors that the Company will ensure that "if this trial fails, it will be for biology, and not for mistakes made along the way, in the design of this trial and the way we analyze it and the way in which we control it, the way everything was run."

160. On June 10, 2021, at the Goldman Sachs Global Healthcare Conference, in discussing the Phase II results for pegcetacoplan in geographic atrophy, Defendant Francois explained that from the Company's inception, in light of historical failures in treating geographic atrophy, Defendants knew that they could not leave any stone unturned:

> [I]n 2015, as a little company in Louisville, Kentucky and with access to relatively little capital, we had to think far ahead. And in a disease like GA, where everything had failed, we told ourselves, okay, we're going to do [a] trial. ***What we cannot afford is to get a half-baked answer. Whether it's negative or positive, we need to know.*** And that was very much the spirit on which FILLY was designed.

161. On the same call, Defendant Francois was asked point-blank "why should someone own Apellis stock in the next 12 months?" In response, Defendant Francois outlined the "unique situation" in "the history of our company" where, in geographic atrophy, Apellis

faced what Francois referred to as "one of the more important . . . clinical readouts this year in all of biotech . . ." with its then-forthcoming DERBY and OAKS studies. Defendant Francois explained that the Company "t[ook] that responsibility very, very seriously" and assured investors, "we are not just ready to take a positive readout and run with it and make a potential drug available to patients globally as quickly as possible[.]"

162. Market adoption of SYFOVRE based on its safety profile was likewise of the utmost importance to investors.

163. During an October 1, 2020, investor call, an analyst from Stifel, Nicolaus & Company, Incorporated asked, "What do you think the efficacy bar is there? I mean, obviously, we know there's nothing approved. But like what do you think would be very clinically meaningful in that population?" Defendant Francois responded, "Yes. So we actually have -- are doing a lot of research on that to kind of understand and prepare for our commercialization. Depending on which physician you ask, they will tell you 20% to 30%. It's generally in that range in terms of reduction over the course of 1 year…"

164. As a Cantor Fitzgerald analyst explained in a September 9, 2021 report: "If approved, a key factor will be how the physician community accepts the drug's profile."

165. Similarly, a September 13, 2021, UBS analyst report discussed the recent study results with physicians, explaining: "His main concern was how to motivate patients to receive injections for only a 12-22% benefit in reduction of GA lesions. He expects, if approved, to offer pegcetacoplan to all his patients and expects a portion to be interested, but sees patient compliance as a question commercially. We continue to think APLS still has real potential for approval and even small market share/low compliance would drive a meaningful commercial opportunity."

166. Of particular importance was whether SYFOVRE was associated with instances of vasculitis. Defendants' knowledge of this is demonstrated by the fact that despite no affirmative obligation to do so, in every instance that they reported on the phase 3 clinical studies, they went out of their way to assure in investors "[n]o events of occlusive or non-occlusive vasculitis or retinitis occlusion were observed over 24 months" in the DERBY and OAKS trials.

167. Analysts noted the significance of these statements. For example, a September 10, 2021 BMO Capital Markets analyst report highlighted: "Safety Ends Up Looking OK….There were 13 cases of intraocular inflammation (0.21% per injection),…and none were associated with retinal vasculitis or retinal vein occlusion." And a September 10, 2021 Needham report stated, "Safety profile better than expected, highlighted by lower than anticipated exudation rates…Intraocular inflammation low (0.21%). No retinal vasculitis, retinal vein occlusion."

**H. No Safe Harbor**

168. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. Many of the specific statements pleaded herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized

and/or approved by an executive officer of the company making the statement who knew that those statements were false or misleading when made.

## V. PLAINTIFFS' CLASS ACTION ALLEGATIONS

169. Plaintiffs brings this class action under Rule 23 of the Federal Rules of Civil Procedure on behalf of a class of all persons and entities who purchased or otherwise acquired Apellis common stock during the Class Period (the "Class"). Excluded from the Class are Defendants, their agents, directors and officers of Apellis, and their families and affiliates.

170. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court.

171. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

a. Whether Defendants violated the Exchange Act;

b. Whether Defendants omitted and/or misrepresented material facts;

c. Whether Defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

d. Whether Defendants knew or recklessly disregarded that their statements were false and/or misleading;

e. Whether the price of Apellis common stock was artificially inflated; and

f. The extent of damage sustained by members of the Class and the appropriate measure of damages.

172. Plaintiffs' claims are typical of those of the Class because Plaintiffs and the Class sustained damages from Defendants' wrongful conduct.

173. Plaintiffs will adequately protect the interests of the Class and has retained counsel who are experienced in securities class actions. Plaintiffs has no interests that conflict with those of the Class.

174. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. Joinder of all Class members is impracticable.

## VI. APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD-ON-THE-MARKET DOCTRINE and *AFFILIATED UTE* PRESUMPTION

175. Plaintiffs will rely upon the presumption of reliance established by the fraud-on-the-market doctrine as outlined in *Basic Inc. v. Levinson*, 485 U.S. 224 (1988) ("*Basic*") and the presumption of reliance for omissions as outlined in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972) ("*Affiliated Ute*").

176. A presumption of reliance the fraud-on-the-market doctrine is appropriate because, among other things:

a. Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

b. The omissions and misrepresentations were material;

c. The Company's common stock traded in an efficient market;

d. The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's common stock; and

e. Plaintiffs and the Class purchased Apellis common stock between the time Defendants misrepresented or failed to disclose material

facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

177. At all relevant times, the market for the Company's common stock was efficient because: (1) as a regulated issuer, the Company filed periodic public reports with the SEC; and (2) the Company regularly communicated with public investors using established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and through other wide-ranging public disclosures, such as

178. 243. As a result of the foregoing, the market for Apellis common stock promptly digested current information regarding Apellis from all publicly available sources and reflected such information in the price of the stock. Under these circumstances, all purchasers of Apellis common stock during the Class Period suffered similar injury through their purchase of Apellis common stock at artificially inflated prices and a presumption of reliance applies.

179. In addition to the fraud-on-the-market presumption, a class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute* because the claims of the Class are grounded on Defendants' material omissions. Because this action involves Defendants' failure to disclose material adverse information that was central to Apellis's operations and prospects – information that Defendants were obligated to disclose – positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here. There will be no difficulty in the management of this action as a class action.

## VII. CLAIMS AGAINST DEFENDANTS

### COUNT I

**Violations of Section 10(b) of the Exchange Act and SEC Rule 10b-5 Promulgated Thereunder Against All Defendants**

180. This Count is asserted against the Defendants for violations of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

181. During the Class Period, Defendants disseminated or approved the materially false and misleading statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

182. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the business, operations and future prospects of the Company as specified herein.

183. Defendants: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements made not misleading; and (c) engaged in acts, practices, and a course of business that operated as a fraud and deceit upon the purchasers of the Company's common stock during the Class Period in an effort to maintain artificially high market price for Apellis's common shares in violation of Section 10(b) of the Exchange Act and Rule 10b-5. Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

184. Each of the Defendants' liability arises from the following facts: (i) the Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) the Defendants, by virtue of their responsibilities and activities as senior officers and/or as a director of the Company, were privy to and participated in the creation, development and reporting of the Company's financial results and prospects; (iii) each of the Defendants was advised of and had access to the Company's management team's internal reports and other data and information at all relevant times; and (iv) each of Defendants was aware of the Company's dissemination of information to the investing public which they knew or recklessly disregarded was materially false and misleading.

185. Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing from the investing public the truth regarding the Company's business prospects and supporting the artificially inflated prices of Apellis's common stock. As demonstrated by Defendants' misstatements of the Company's business and prospects during the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

186. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of Apellis's common stock was artificially inflated during the Class Period. In ignorance of the fact that the market

prices of Apellis's common stock was artificially inflated, and relying directly or indirectly on the false and misleading statements made by the Defendants, or upon the integrity of the markets in which the securities trade, and/or on the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiffs and the other members of the Class purchased Apellis common stock during the Class Period at artificially high prices and were damaged as a result of the securities law violations alleged herein.

187. At the time of said misrepresentations and omissions, Plaintiffs and the other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiffs and the other members of the Class and the marketplace known the truth regarding the significant problems alleged herein, which were not disclosed by Defendants, Plaintiffs and the other members of the Class would not have purchased or otherwise acquired Apellis common stock, or, if they had purchased such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

188. By virtue of the foregoing, Defendants violated Section 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder. As a direct and proximate result of the Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their purchases of Apellis common stock during the Class Period.

## COUNT II

### Violations of Section 20(a) of the Exchange Act Against Defendant Francois

189. This Count is asserted against Defendant Francois for violations of Section 20(a) of the Exchange Act. Plaintiffs repeat and reallege each and every allegation above as if fully set forth herein.

190. Defendant Francois acted as a controlling person of Apellis within the meaning of Section 20(a) of the Exchange Act. By virtue of his high-level position, and his ownership and contractual rights, participation in and/or awareness of the Company's operations, and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, Defendant Francois had the power to influence and control—and did influence and control, directly or indirectly—the decision-making of the Company, including the content and dissemination of the various false and/or misleading statements. Defendant Francois was provided with or had unlimited access to copies of the Company's reports and other statements alleged by Plaintiffs to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

191. In particular, Defendant Francois had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular accounting practices giving rise to the securities violations as alleged herein, and exercised the same.

192. As described above, the Company and Defendant Francois each violated Section 10(b) of the Exchange Act and SEC Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of his position as a controlling person, Defendant Francois is liable under Section 20(a) of the Exchange Act. As a direct and proximate result of this wrongful conduct, Plaintiffs and other members of the Class suffered damages in connection with their purchases of Company common stock during the Class Period.

## VIII. PRAYER FOR RELIEF

**WHEREFORE**, Plaintiffs pray for relief and judgment, as follows:

A. Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

B. Awarding compensatory damages and equitable relief in favor of Plaintiffs and other members of the Class against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Such other and further relief as the Court may deem just and proper.

## IX. JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury.

February 8, 2024

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